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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
Fax: 504-253-4560

December 19, 2002

WARNING LETTER NO. 2003-NOL-05

FEDERAL EXPRESS
NEXT DAY DELIVERY

Mr. Joe K. Guy, Owner/President
Southwest Pharmacy/DBA Anchor Home Care
1220 LaSalle Street
McComb, Mississippi 39648

Dear Mr. Guy:

During the November 8 and 15, 2002, inspection of your facility, located at 1220 LaSalle Street, McComb, Mississippi, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the controls used for the manufacturing, processing, packing or holding of this product are not in conformance with CGMP regulations, found in Title 21, *Code of Federal Regulations*, Part 211 (21 C.F.R. Part 211).

Specific observations made during the inspection include:

1. You failed to obtain a required certificate of analysis for each bulk cylinder of medical oxygen received [21 C.F.R. § 211.165(a)]. There was no documentation that [redacted] bulk medical oxygen cylinders had been tested for purity, strength, and quality as required by your firm's written procedures, and full USP testing was not performed on the finished product [21 C.F.R. § 211.84(d)(2)]. There was no documentation that identity and purity tests were performed for [redacted] medical oxygen cylinders, which were filled as a part of five lots manufactured between March 2000 and May 2002 [21 C.F.R. § 211.188(b)(5)].

2. You failed to provide and document adequate training of your employees in the particular operations they perform, as required by the CGMP regulations [21 C.F.R. § 211.25(a)].

3. You failed to follow your written process control procedures in the execution of production and process control functions and in the testing of drug product containers [21 C.F.R. § 211.100(b)]. You also failed to handle and store drug product containers, at all times, in a manner to prevent contamination [21 C.F.R. § 211.80(b)].

4. You have not established a quality control unit with the responsibility and authority to approve or reject all components, drug product containers, labeling, and all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product [21 C.F.R. §

211.22(a)]. Additionally, there was no documentation of the review and approval of your written procedures [21 C.F.R. § 211.100(a)].

5. You have not documented routine calibration and equipment checks, at suitable intervals, according to a written program designed to assure proper performance [21 C.F.R. § 211.68(a)]. You do not have a manufacturer's instruction manual describing the calibration and use of the [redacted] used for finished product testing [21 C.F.R. § 211.160(b)(4)].

6. Your batch production and control records failed to include complete information relating to the production and control of each batch of medical oxygen filled (21 C.F.R. § 211.188). These batch production and control records were not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch was released or distributed. The last documented production record review was dated July 13, 1999, (21 C.F.R. § 211.192).

7. You failed to establish a system by which the distribution of each lot of medical oxygen can be readily determined to facilitate its recall, if necessary [21 C.F.R. § 211.150(b)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the CGMP regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. However, it is necessary that you notify this office in writing, within 15 working days of the receipt of this letter, of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Cynthia R. Crocker, Compliance Officer, U.S. Food and Drug Administration, at 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Crocker at telephone number (601) 965-4581.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483